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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,171	04/16/2002	Andrew Lever	117-372	8487
23117	7590	06/15/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/009,171

Applicant(s)

LEVER ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-9, 10, 12- 15, 17, 18, 20- 26 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6, 12- 15, 17, 18, 20- 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7- 10, and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This action is in response to the paper filed

This action is on claims 7- 10, and 24-26.

### ***Objection to the Specification***

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code.

Applicant has transfigured the link to be non-standard format and the objection is maintained because either the reference to it must be removed or the material cited must be added to the specification if it is needed and does not constitute new matter.

There is no guarantee that the material contained in the link will be in the future and the Office has no control over the material.

### ***Sequence Requirements***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on as follows:

The specification does not contain sequence identifiers (SEQ ID#s) in all locations where sequences are disclosed, see at least page 24 and Figures 3a- 3e. The sequence shown in the figures is not identified by a SEQ ID# in the figure or in the Brief Description of the Figures section.

Applicant has amended the specification to include SEQ ID3s.

***Claim Objections***

Claim 10 is objected to because of the following informalities: the claim should read ....therapeutic..., or antigenic .... The underlined portions indicate suggestions to fix grammatical agreement. Appropriate correction is required.

Applicant has fixed the claim and the objection is withdrawn.

***Rejections Maintained***

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7, 8, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that there is written description and points to SEQ ID#1 and one fragment as well as says that variants are also shown and points to figure 3.

Applicants arguments have been fully considered and found persuasive in part.

SEQ.ID#1 is described and one fragment, bases 53-85 of SEQ ID#1.

Applicant points to Figure 3 (really Figure 3A-3D) as support for variants. The figures do not show variants but RNA folding of specific mutants. The specification does not appear to define variants or limit them to the mutants of Figure 3A-3D. Variants can be any change at any position(s) of the packaging signal or deletions/additions of one or more base at one or more positions.

Applicant has not shown any fragments of 10 or more that have the packaging signal function or variants of either.

Thus, the rejection is maintained.

### ***Claim Rejections - 35 USC § 102***

Claims 7, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rizvi *et al.* (IDS).

Applicant argues that Rizvi *et al.* do not teach what is necessary or sufficient for packaging, that they do not teach SEQ ID#1, that they use HIV-1 to encapsidate, and that packaging is a non-reciprocal event as shown by Kaye and Lever.

Applicant's arguments have been fully considered and not found persuasive.

The claims are drawn to a packaging vector, there are no requirements for minimum packaging sequences (the claims use comprising language), and the claims are drawn to a vector only and are not drawn to a method where the vector is packaged by a certain kind of virus. The constructs of Rizvi *et al.* contain part of SEQ ID#1.

The vectors of Rizvi *et al.* contain at least 10 nucleotides of SEQ ID#1 as well as variants, including the pbs, SD, and whole 5' leader and is packaged.

The claims are not drawn to minimum packaging sequences or methods of efficient vector packaging or gene delivery.

Thus, Rizvi *et al.* anticipate the claimed invention.

Claims 7, 8, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Lauermann (US 6635472).

Applicant argues that there is no specific teaching of SIV vectors in the document and that the document does not contain SEQ ID#1 or fragments or variants.

Applicants arguments have been fully considered and not found persuasive.

The claims are not limited to consisting of only SEQ ID#1. The claims are drawn to a vector that comprises a packaging signal and can be SIV. The limitations of fragments or variants do not exclude the reference. The instant claims are not limited to specific sequences for packaging signals because of the language "comprising".

Thus, Lauermann anticipate the claimed invention.

### ***Rejections Necessitated By Amendment***

#### ***New Claim Objections***

Claims 24-26 are objected to because of the following informalities: they depend from a rejected claim. Appropriate correction is required.

#### ***Allowable Subject Matter***

Claims 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
June 7, 2005

  
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6/13/05